General

Guideline Title

Preoperative and pretreatment investigations for malignant melanoma.

Bibliographic Source(s)

Alberta Provincial Cutaneous Tumour Team. Preoperative and pretreatment investigations for malignant melanoma. Edmonton (Alberta): CancerControl Alberta; 2013 Feb. 9 p. (Clinical practice guideline; no. CU-007). [8 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Alberta Provincial Cutaneous Tumour Team. Preoperative and pretreatment investigations for malignant melanoma. Edmonton (Alberta): Alberta Health Services, Cancer Care; 2012 Mar. 8 p. (Clinical practice guideline; no. CU-007). [6 references]

Recommendations

Major Recommendations

For staging definitions please refer to the Appendix in the original guideline document.

Clinical Presentation and Preliminary Work-up (National Comprehensive Cancer Network [NCCN], 2012)

Once melanoma has been confirmed, each of the following should be documented, as per the College of American Pathologists (CAP) Protocol for the Examination of Specimens from Patients with Melanoma of the Skin (CAP, 2011):

- Breslow thickness (specify mm, indeterminate)
- Ulceration (present, not identified, indeterminate)
- Clark level
- Microscopic satellitosis (not identified, present, indeterminate)
- Macroscopic pigmentation (optional; not identified, present, present, patchy/focal, indeterminate)
- Mitotic rate (less than 1 per mm^2 or specify number per mm^2)
- Peripheral and deep margin status of biopsy (cannot be assessed, uninvolved by invasive melanoma, involved by invasive melanoma, uninvolved by melanoma in situ, involved by melanoma in situ)
- Specimen laterality (right, left, midline, not specified)
- Tumour site
- Tumour size
- Tumour regression (not identified, present involving less than 75% of lesion, present involving 75% or more of lesion, indeterminate)

- Histologic sub-type (melanoma not otherwise classified, superficial spreading melanoma, nodular melanoma, lentigo maligna melanoma, acral-lentiginous melanoma, desmoplastic and/or desmoplastic neurotropic melanoma, melanoma arising from blue nevus, melanoma arising in a giant congenital nevus, melanoma of childhood, nevoid melanoma, persistent melanoma, other)
- Tumour infiltrating lymphocytes (optional; not identified, present non-brisk, present brisk)
- Growth phase (optional; radical, vertical, indeterminate)
- Lymph-vascular invasion (not identified, present, indeterminate)
- Perineural invasion (optional; not identified, present, indeterminate)

Preliminary work-up should then include the following:

- History and physical exam (H&P) with attention to locoregional area, draining lymph nodes, and skin type
- Complete skin exam
- Family history of melanoma, prior primary melanoma, atypical moles, or dysplastic nevi

Work-up by Clinical Stage (NCCN, 2012)

Stage 0, *in situ* (Tis, N0, M0)

- None

Stage IA, Low Risk Primary (≤1.0 mm thick, without ulceration and mitotic index <1/mm^2) N0, M0

- Further imaging (computed tomography [CT] scan, positron emission tomography [PET], magnetic resonance imaging [MRI]) only to evaluate specific signs or symptoms
- Consider discussion of sentinel node biopsy

Stage IB, Intermediate Risk Primary (≤1.0 mm thick, with ulceration or mitotic index ≥1/mm^2 or 1.01–2.0 mm thick without ulceration) N0, M0

- Chest x-ray (optional; however, for tumours >4 mm, baseline chest x-ray is indicated)
- Further imaging to evaluate specific signs or symptoms for stage IIB, IIC patients (CT scan, PET, MRI)

Stage II, High Risk Primary (1.01–1.0 mm thick with ulceration or >2.01 mm thick any ulceration) N0, M0

- Chest x-ray (optional; however, for tumours >4 mm, baseline chest x-ray is indicated)
- Further imaging to evaluate specific signs or symptoms for stage IIB, IIC patients (CT scan, PET, MRI)

Stage III (any thickness), N1a-3 (sentinel lymph node), M0

- Consider baseline imaging (abdominal/chest imaging: x-ray, CT ± PET) and to evaluate specific signs or symptoms
- Lactate dehydrogenase (LDH) (optional)

Stage III (any thickness) ≥N1 (clinical), M0

- Fine needle aspiration (FNA) preferred, if feasible, or lymph node biopsy
- Consider baseline imaging (abdominal/chest imaging: x-ray, CT ± PET) and to evaluate specific signs or symptoms
- LDH (optional)

Stage III In-transit (any thickness) N3, M0

- Biopsy preferred; FNA if biopsy not possible
- Consider baseline imaging (abdominal/chest imaging: x-ray, CT ± PET) and to evaluate specific signs or symptoms
- LDH (optional)

Stage IV Metastatic

- FNA preferred, if feasible or biopsy
- Chest x-ray and/or chest CT
- LDH
- Recommend abdominal and pelvic CT with MRI or CT of head, and/or PET
- Further imaging studies to evaluate specific signs or symptoms

Recurrences

True Local Scar Recurrence

- Biopsy to confirm
- Chest x-ray optional
- Complete blood count (CBC), LDH optional
- CT scan, PET, MRI, as indicated

Local, Satellitosis, and/or In-transit Recurrence

- FNA (preferred) or excisional biopsy
- Chest x-ray and/or chest CT
- CBC, LDH optional
- Pelvic CT if inguinofemoral nodes clinically positive
- Other CT scans or other imaging studies if clinically indicated

Nodal Recurrence

- FNA (preferred) or lymph node biopsy
- Chest x-ray and/or chest CT
- LDH
- Pelvic CT if inguinofemoral nodes clinically positive
- Abdominal and pelvic CT ± MRI head, PET scan as indicated

Distant Recurrence

- FNA (preferred) or biopsy
- Chest x-ray and/or chest CT
- LDH
- Abdominal/pelvic CT, MRI brain, PET scan as indicated

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Malignant melanoma

Guideline Category

Evaluation

Clinical Specialty

Dermatology

Oncology

Pathology

Radiology

Surgery

Intended Users

Advanced Practice Nurses

Clinical Laboratory Personnel

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To develop a consensus based guideline that outlines which tests should be included in the pre-operative and pre-treatment investigation ('work-up') of patients with malignant melanoma

Target Population

Adults over the age of 18 years with malignant melanoma

Note: Different principles may apply to pediatric patients.

Interventions and Practices Considered

1. Preliminary work-up
    - Examination and documentation of melanoma specimens as per the College of American Pathologists Protocol for the Examination of Specimens from Patients with Melanoma of the Skin
    - History and physical examination with attention to locoregional area, draining lymph nodes, and skin type
    - Complete skin exam
    - Family history of melanoma, prior primary melanoma, atypical moles, or dysplastic nevi
2. Additional work-up (varies by clinical stage)
    - Imaging (computed tomography [CT] scan, positron emission tomography [PET], magnetic resonance imaging [MRI], chest x-ray)
    - Sentinel node biopsy
    - Lactate dehydrogenase (LDH)
    - Fine needle aspiration (FNA) or lymph node biopsy
    - Complete blood count

Major Outcomes Considered

- Sensitivity and specificity of diagnostic tests
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Research Questions

Specific research questions to be addressed by the guideline document were formulated by the guideline lead(s) and Knowledge Management (KM) Specialist using the PICO question format (Patient or Population, Intervention, Comparisons, Outcomes).

Guideline Question

Which tests should be included in the work-up of patients with malignant melanoma?

Search Strategy

The MEDLINE (1966 through January 5, 2011), CINAHL, Cochrane, American Society of Clinical Oncology (ASCO) Abstracts and proceedings, and CANCERLIT databases were searched. The search included practice guidelines, systematic reviews, meta-analyses, randomized controlled trials, and clinical trials. Search terms included: magnetic resonance imaging, computed tomography, positron emission tomography, imaging, sentinel node biopsy, chest x-ray, lactate dehydrogenase, fine needle aspiration, biopsy, complete blood count, or pre-operative and melanoma.

For the 2013 update of the guideline, PubMed was searched for evidence on imaging and blood work for cutaneous melanoma. The search term "melanoma" was used and results were limited to clinical trials, published between January 2012 and January 2013. Citations were hand-searched for studies pertaining to imaging and blood work, resulting in a total of two prospective studies.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Not stated

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Evidence was selected and reviewed by a working group comprised of members from the Alberta Provincial Cutaneous Tumour Team and a Knowledge Management (KM) Specialist from the Guideline Utilization Resource Unit (GURU). A detailed description of the methodology followed during the guideline development process can be found in the Guideline Utilization Resource Unit Handbook (see the "Availability of Companion Documents" field).

Evidence Tables

Evidence tables containing the first author, year of publication, patient group/stage of disease, methodology, and main outcomes of interest are assembled using the studies identified in the literature search. Existing guidelines on the topic are assessed by the KM Specialist using portions of the Appraisal of Guidelines Research and Evaluation (AGREE) II instrument (http://www.agreetrust.org) and those

meeting the minimum requirements are included in the evidence document. Due to limited resources, GURU does not regularly employ the use of multiple reviewers to rank the level of evidence; rather, the methodology portion of the evidence table contains the pertinent information required for the reader to judge for himself the quality of the studies.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Formulating Recommendations

The working group members formulated the guideline recommendations based on the evidence synthesized by the Knowledge Management (KM) Specialist during the planning process, blended with expert clinical interpretation of the evidence. As detailed in the Guideline Utilization Resource Unit Handbook (see the "Availability of Companion Documents" field), the working group members may decide to adopt the recommendations of another institution without any revisions, adapt the recommendations of another institution or institutions to better reflect local practices, or develop their own set of recommendations by adapting some, but not all, recommendations from different guidelines.

The degree to which a recommendation is based on expert opinion of the working group and/or the Provincial Tumour Team members is explicitly stated in the guideline recommendations. Similar to the American Society of Clinical Oncology (ASCO) methodology for formulating guideline recommendations, the Guideline Utilization Resource Unit (GURU) does not use formal rating schemes for describing the strength of the recommendations, but rather describes, in conventional and explicit language, the type and quality of the research and existing guidelines that were taken into consideration when formulating the recommendations.

Following a review of the evidence by the Alberta Provincial Cutaneous Tumour Team, no changes were made to the recommendations.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A study looking at the cost-effectiveness of positron emission tomography-computed tomography (PET-CT), CT only, and PET only as staging tests among melanoma patients with palpable proven lymph node metastases, found that CT alone decreased the cost of treatment by 5.5%, whereas PET alone and CT-PET increased the cost of diagnostic work-up and treatment by 7.2% and 15.1% respectively.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

This guideline was reviewed and endorsed by the Alberta Provincial Cutaneous Tumour Team.

When the draft guideline document has been completed, revised, and reviewed by the Knowledge Management (KM) Specialist and the working group members, it will be sent to all members of the Provincial Tumour Team for review and comment. This step ensures that those intended to use the guideline have the opportunity to review the document and identify potential difficulties for implementation before the guideline is finalized. Depending on the size of the document, and the number of people it is sent to for review, a deadline of one to two weeks will usually be given to submit any feedback. Ideally, this review will occur prior to the annual Provincial Tumour Team meeting, and a discussion of the proposed edits will take place at the meeting. The working group members will then make final revisions to the document based on the received feedback, as appropriate. Once the guideline is finalized, it will be officially endorsed by the Provincial Tumour Team Lead and the Executive Director of Provincial Tumour Programs.

Evidence Supporting the Recommendations

References Supporting the Recommendations

College of American Pathologists. Protocol for the examination of specimens from patients with melanoma of the skin. Version 3.1.0.0. Northfield (IL): College of American Pathologists; 2011 Feb 1. 18 p. [31 references]

National Comprehensive Cancer Network (NCCN). Melanoma guidelines, v.1.2012. Fort Washington (PA): National Comprehensive Cancer Network (NCCN); 2012.

Type of Evidence Supporting the Recommendations

The recommendations are supported by existing guidance.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Pre-operative or pre-treatment investigations in patients with malignant melanoma are important for establishing baseline values, confirming or re-evaluating treatment plans, or possibly identifying patients who may be suitable for inclusion in a clinical trial.

Potential Harms

In general, care must be taken when interpreting the results of blood or imaging tests, given the relatively low sensitivity of some of these tests.

Qualifying Statements

Qualifying Statements

The recommendations contained in this guideline are a consensus of the Alberta Provincial Cutaneous Tumour Team and are a synthesis of currently accepted approaches to management, derived from a review of relevant scientific literature. Clinicians applying these guidelines should, in consultation with the patient, use independent medical judgment in the context of individual clinical circumstances to direct care.

Implementation of the Guideline

Description of Implementation Strategy

- Present the guideline at the local and provincial tumour team meetings and weekly rounds.
- Post the guideline on the Alberta Health Services website.
- Send an electronic notification of the new guideline to all members of CancerControl Alberta.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Identifying Information and Availability

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2012 Mar (revised 2013 Feb)

Guideline Developer(s)

CancerControl Alberta - State/Local Government Agency [Non-U.S.]

Source(s) of Funding

CancerControl Alberta

There was no direct industry involvement in the development or dissemination of this guideline.

Guideline Committee

Alberta Provincial Cutaneous Tumour Team

Composition of Group That Authored the Guideline

Members of the Alberta Provincial Cutaneous Tumour Team include dermatologists, medical oncologists, radiation oncologists, surgical oncologists, nurses, pathologists, and pharmacists.

Financial Disclosures/Conflicts of Interest

Participation of members of the Alberta Provincial Cutaneous Tumour Team in the development of this guideline has been voluntary and the

authors have not been remunerated for their contributions. CancerControl Alberta recognizes that although industry support of research, education and other areas is necessary in order to advance patient care, such support may lead to potential conflicts of interest. Some members of the Alberta Provincial Cutaneous Tumour Team are involved in research funded by industry or have other such potential conflicts of interest. However the developers of this guideline are satisfied it was developed in an unbiased manner.

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Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the Alberta Health Services Web site .

Availability of Companion Documents

The following is available:

- Guideline utilization resource unit handbook. Edmonton (Alberta): CancerControl Alberta; 2013 Jan. 5 p. Electronic copies: Available in Portable Document Format (PDF) from the Alberta Health Services Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on December 10, 2012. The information was verified by the guideline developer on January 23, 2013. This summary was updated by ECRI Institute on April 28, 2014. The updated information was verified by the guideline developer on June 6, 2014

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